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FOR

COMPOSITION FOR INCREASING BONE DENSITY

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# COMPOSITION FOR INCREASING BONE DENSITY

## BACKGROUND

### Cross-Reference to Related Application

**[0001]** The application is a Continuation co-pending Application Serial No. 09/365,156, filed July 30, 1999 by applicants, Samuel L. Forusz, Hanlan Liu, and Rose M. Muatine, entitled "Composition for Increasing Bone Density".

### Field

**[0002]** The invention relates to nutritional supplements and more particularly to a composition and method for reducing the risks associated with bone density loss, e.g., the risks of osteoporosis.

### Description of Related Art

**[0003]** Osteoporosis is a debilitating disease affecting as many as one in three women after menopause. The disease affects the skeletal structure making the skeletal structure weak and frail. Calcium and magnesium supplementation is seen as one way to protect against osteoporosis. Men also experience a loss in bone density with age. Accordingly, health care practitioners increasingly encourage calcium and magnesium supplementation for men and women of all ages.

**[0004]** In general, only about 30 percent of dietary calcium is absorbed by the body and deposited in the bone. Improved calcium (and magnesium) absorption in the body would have important consequences in the reduction of osteoporosis and bone fractures.

**[0005]** Several calcium and/or magnesium supplements have been introduced in recent years. U.S. Patent No. 5,389,387 issued to Zuniga, et al. and U.S. Patent No. 5,401,524 issued to Burkes, et al. describe a calcium beverage supplement

composition. These compositions combine malic acid and citric acid with a calcium syrup such as calcium lactate. The malic acid and citric acid provide stability against precipitation of the calcium salt, as well as taste and mouth feel quality. U.S. Patent No. 5,424,321 issued to Shlyankevich and U.S. Patent No. 5,654,011 issued to Jackson, et al. describe beverage compositions including calcium, Vitamin D, magnesium, and zinc.

**[0006]** Soy isoflavones are another group of dietary acceptable compounds believed to be beneficial in the treatment and/or prevention of osteoporosis. U.S. Patent No. 5,424,321 describes a composition for the treatment or prevention of osteoporosis that utilizes soy bean food products that contain natural phytoestrogens of the isoflavone or coumestan groups. The isoflavones include daidzein, genistein, and glycitein. The classes of isoflavones can also be derived synthetically. The patent claims that the soy isoflavones are effective in preventing osteoporosis by provoking an estrogenic response in post-menopausal women.

**[0007]** In general, it is believed that the majority of calcium and magnesium absorption occurs in the intestines. Certain oligosaccharides, including inulin, are believed to stimulate mineral absorption in humans. Oligosaccharides are also believed to increase the bifidobacteria population in the large intestine including the colon, contributing to beneficial effects in humans, including a reduction of harmful bacteria, toxic metabolites, and detrimental enzymes.

**[0008]** What is needed is a composition that improves the calcium and magnesium absorption in humans to increase bone density and reduce the risk of osteoporosis.

## SUMMARY

**[0009]** An improved supplement composition and a method of reducing bone density loss is disclosed. In one aspect, a composition suitable for human consumption combines a dietary acceptable amount of a calcium compound, a dietary acceptable amount of a magnesium compound, inulin, and a dietary acceptable amount of Vitamin D<sub>3</sub>. In another aspect, the composition includes at least one soy isoflavone. Other components suitable for a composition with or without soy isoflavones include, but are not limited to, minerals such as phosphorus and zinc; vitamins including Vitamin C (ascorbic acid) and Vitamin K; stabilizing agents; acidifiers; and sweeteners.

**[0010]** The composition may be in the form of a ready to drink beverage, a beverage preparation of a dry mix or syrup concentrate, a wafer, a paste, a bar, or a cookie. The composition may also contain a variety of levels of the individual components. For example, a desired daily amount of the individual components of the composition has been determined. This amount may be administered as a single dose or as several doses. Where the composition is a beverage, for example, the beverage may constitute, for example, one-eighth of a predetermined daily amount of the individual components, making the beverage suitable for consumption eight times daily as in the recommended daily amount of water intake.

**[0011]** In one aspect of a beverage form, the composition maximizes the solubility of the components by, in one embodiment, including a stabilizing agent of at least one of maltol, a composition of carrageenan and maltodextrin, or xanthan gum. The beverage composition may be a clear or a colored solution without significant residue or sediment (e.g., generally translucent). The beverage is also, preferably, adjusted to a pH between 3 and 7 and more preferably between pH 4 and 5 at room temperature with an acidifier in an amount up to the equivalent amount of a calcium of the calcium compound in the composition.

[0012] As a method of reducing the risk of bone density loss, a composition suitable for human consumption comprising a portion of the daily predetermined amount of a calcium compound, a magnesium compound, and inulin, with optionally other components including, but not limited to, phosphorus, Vitamin D<sub>3</sub>, Vitamin K, a zinc compound, and ascorbic acid may be administered. The composition may be administered in various forms, including as a beverage, a paste, a bar, or a cookie. The amount of the individual components of the composition may be adjusted to provide a portion, including the entire portion, of a predetermined beneficial amount, such as a recommended daily amount.

## DETAILED DESCRIPTION

[0013] A composition that includes a supplement to provide dietary needs of individuals for nutrients to support adequate bone density and a healthy skeletal system is described. The composition also provides appropriate nutrients to reduce the risk of osteoporosis or to treat bone density loss associated with osteoporosis. A method of reducing the risk of bone density loss commonly associated with the development or onset of osteoporosis is also described.

[0014] In one embodiment, the composition comprises inulin, minerals and optionally one or more vitamins. More particularly, the composition includes a dietary acceptable amount of a calcium compound and a magnesium compound, inulin, and a dietary acceptable amount of Vitamin D<sub>3</sub>. In another embodiment, the composition also includes one or more soy isoflavones.

[0015] Calcium and magnesium are important in supporting a healthy skeleton system, by building bone mass. There are a variety of calcium and magnesium salts that are suitable for human consumption and are suitable for contributing to bone growth according to the invention. Suitable calcium salts include, but are not limited to, calcium lactate and calcium gluconate. Suitable magnesium salts include, but are not limited to, magnesium glycerophosphate, magnesium sulfate and magnesium phosphate. Magnesium glycerophosphate is a desired choice of the magnesium salt because magnesium glycerophosphate also contributes a phosphorous component to the composition. However, suitable phosphorus may be added separately from magnesium. Phosphorus salts include, but are not limited to, monosodium phosphate. Phosphorous is believed to contribute to bone density and a healthy skeletal system.

[0016] Isoflavones are a dietary source for increasing bone density. The isoflavones suitable for the invention include, but are not limited to, the naturally occurring soy isoflavones from soy including the classes such as daidzein, genistein, and glycitein in a variety of forms (e.g., glycosidic and acetylated forms). Soy isoflavones are commercially available, for example, from Archer

Daniels Midland of Decatur, Illinois. Synthetically derived isoflavones may also be suitable.

**[0017]** Oligosaccharides include, but are not limited to, fructo-oligosaccharides and gluco-oligosaccharides. Inulin, a fructo-oligosaccharide is derived principally from chickory root. Oligosaccharides such as inulin provide at least two benefits. First, oligosaccharides increase the intestinal absorption of minerals, such as calcium and magnesium. Second, oligosaccharides improve the intestinal microflora by increasing the amount of colonic bifidobacteria. Inulin as an oligosaccharide source is commercially available, for example, from Imperial Suiker Unier of Sugar Land, Texas.

**[0018]** Vitamin D<sub>3</sub> stimulates intestinal absorption of minerals, particularly calcium, and calcium mobilization. Cold water soluble (CWS) Vitamin D<sub>3</sub> (cholecalciferol) is available commercially as from BASF Corporation of Paramus, New Jersey, or Hoffmann-La Roche of Nutley, New Jersey.

**[0019]** In addition to the above components, a composition may also include, but is not limited to, additional minerals such as phosphorous and zinc. Phosphorous, as noted above, promotes bone density. Zinc may be added, in particular, to offset any impact on zinc absorption caused by calcium uptake. Vitamins including Vitamin C (ascorbic acid) and Vitamin K (phylloquinone) may also be added to the composition. Vitamin C helps utilize the absorbed calcium and maintains normal calcium crystals in bones. Vitamin K is believed to reduce the urinary excretion of calcium and the production of bone resorbing agents such as prostaglandin E2 or interleukin 6. Additional components such as stabilizing agents, acidifiers, and sweeteners may further be added.

**[0020]** The composition can take many forms. These forms include, a ready-to-drink beverage or a portion, including (USDA government approved) the entire portion, of the predetermined requirements (e.g., recommended daily requirements) for maximizing the intake and utilization of bone building (e.g., bone density promoting) materials such as calcium, magnesium, and inulin. The composition may also take the form of a beverage preparation of, for example, a

dry mix or a concentrate syrup to be mixed with a liquid such as water, milk, or juice. In this manner, a more concentrated form of the composition may be packaged to be diluted with a liquid. Still further, the composition may take the form of a paste that may be spread on a wafer such as a sweet wafer (e.g., cookie) or a cracker. Yet further, a composition of the invention may be encompassed in the form of a cookie or bar. It is to be appreciated that in these other forms (e.g., paste, bar, cookie, etc.), the composition may constitute the entire portion of a predetermined amount (e.g., recommended daily amount) of the components or a smaller portion of such predetermined amount. Still further, it should be appreciated that other forms of the composition may be contemplated. For example, dietary forms such as cereals or candies may also be utilized.

**[0021]** In one embodiment, the composition is a beverage comprising the entire portion or a smaller portion of the daily predetermined quantity of the desired components of the composition for increasing bone density and/or reducing the risk of osteoporosis.

**[0022]** In particular, the composition of a beverage comprises, in one example, a portion of the individual components corresponding to a predetermined daily amount dosage recommending eight servings per day. In this example, eight servings are chosen with the objective that an ordinary person will take around eight 240 mL dosages daily.

**[0023]** Table 1 represents a suitable range of the daily amount of individual components of one composition.

**[0024]** **Table 1:** Predetermined Daily Amounts

Calcium	500-2000 mg
Magnesium	100-700 mg
Isoflavones (soy)	50-200 mg
Inulin	5-20 g
Vitamin D3	400-800 IU (1 IU=0.025 µg)
Vitamin K	35-85 µg
Vitamin C	200-1000 mg
Zinc	4-30 mg

[0025] In one embodiment, the composition as a beverage includes a stabilizing agent to facilitate the solubilization of the individual components in solution. The stabilizing agent is one or more of a maltol commercially available from Cultor Food Science, Inc. of Ardsley, New York. A composition of carrageenan and maltodextrin such as sold under the trademark INSTA\*THICK C-15L™ by Zumbro Inc. of Hayfield, Minnesota, or a xanthan gum such as sold under the trademark KELTROL™, by NutraSweet Kelco Company of Deerfield, Illinois. Preferably, a composition is combined with a combination of maltol and a composition of carrageenan and maltodextrin or a composition of maltol and xanthan gum(s). In this manner, the solubility of the individual components of the composition, particularly soy isoflavones, is improved. A suitable range of maltol in a beverage composition is 0.1 g to 0.4 g for a 240 mL composition. In a composition such as described including soy isoflavones, the level of 0.1 g in 240 mL aqueous solution was found to increase the solubility of individual components including the soy isoflavones in aqueous solution. A suitable range of a composition of carrageenan and maltodextrin commercially available under the trademark INSTA\*THICK is 1.0 g to 4.0 g for a 240 mL composition. The level of 1 g in 240 mL water was found to increase the solubility of the components in aqueous solution. A suitable range of xanthan gum commercially available under the trademark KELTROL-T is 0.024 g to 0.096 g for a 240 mL composition. The level of 0.024 g in 240 mL aqueous solution generally does not create a viscous mouthfeel. The 0.096 usage level is used in the preparation of 4x concentrated syrup.

[0026] Table 2 shows the combination of maltol and INSTA\*THICK C-15L™ increases the solubility of three soy isoflavones, particularly genistin (>75%), in aqueous solution as assayed by high performance liquid chromatography. Microfiltration through a membrane with pore size from 0.45 to 1.2  $\mu\text{m}$  resulted in clarified solutions with less precipitation compared with non-microfiltered ones as shown in Table 3.

**[0027]** **Table 2:** Comparison of percent recovery of three soy isoflavones in the filtrate with and without maltol and/or INSTA\*THICK C-15L™.

Soy Isoflavone	% Recovery No additives	% Recovery with maltol	% Recovery with INSTA*THICK C-15L™	% Recovery with maltol and INSTA*THICK C-15L™
Daidzin	93.26%	98.70%	98.94%	97.64%
Glycitin	96.60%	99.23%	101.04%	98.75%
Genistin	59.07%	77.77%	76.69%	74.28%

**[0028]** **Table 3:** Comparison of turbidity of filtered and nonfiltered samples measured by turbidimetry using spectrophotometer.

Samples	Absorption at 457nm
Microfiltration through glass fiber membrane with a pore size of 0.7 $\mu$ m	0.160
Non-microfiltration	0.125

**[0029]** Different levels of sweeteners (such as, but not limited to, sugars, sugar alcohols, monosaccharides, disaccharides, trisaccharides) and different flavors may be used in the beverage composition. The composition can be formed as a low calorie composition with artificial sweeteners such as, but not limited to, ASPARTAME™, ACESULFAME-K™, SACCHARIN™, or SUCRALOSE™ or any combination of the above. Appropriate flavors include, but are not limited to, orange, peach, cranberry, tangerine, raspberry, grapefruit, mango, black cherry, strawberry, or any combination of the above flavors. The beverage may be clear, colorless, translucent, and/or contain a colorant. Suitable colorants can be from natural sources or from certified F&DC colorants.

**[0030]** In one embodiment, the flavor characteristics are selected for optimum compatibility with other ingredients, particularly inulin, optional soy isoflavone, optional vitamins and minerals (e.g., calcium, magnesium, etc.), to achieve a superior taste profile.

**[0031]** The composition, in one embodiment, is adjusted to be at a pH less than 7, and preferably between 3 and 7, and more preferably between 4 and 5. The addition of an acidifier such as a combination of malic acid and citric acid to one embodiment of the composition is utilized to adjust the pH from about 4 to about 7 (preferably below 4.6) and to overcome precipitation problems associated with

prior art compositions. The pH of the beverage product between 4 and 5 is suitable because inulin is stable in solution above pH 4 at room temperature. Also, this medium-high acid (i.e., pH < 4.6) of the beverage is desirable for bacterial control.

**[0032]** In one embodiment of a beverage composition wherein the individual components of the composition are soluble (e.g., a generally translucent beverage), the acidifier is present in an amount up to the equivalent amount of a calcium component. Examples 1 through 7 described herein present embodiments where the amount of calcium (0.05/240)(100) and the amount of acidifier ((0.336 citric acid + 0.172 malic acid)/240)(100) are each 0.21 percent.

**[0033]** One approximate ratio of a composition including a calcium compound, a magnesium compound, soy isoflavones, and the oligosaccharide inulin relative to one another is shown in Table 4.

**[0034]** **Table 4:** Ratio of components in a composition

Components	Ratio
Ca:Mg	5:1 to 3:1
Ca:soy isoflavones	10:1
Ca:inulin	1:10
Mg:soy isoflavones	2:1 to 3:1
Mg:inulin	1:50 to 1:30
Soy isoflavones:inulin	1:100
Zinc	4-30 mg

**[0035]** Representative compositions of suitable beverages are provided. In the following ranges, the lower value represents a 240 mL composition containing one-eighth of a preferred predetermined dosage level and the upper value is a 4x concentrate of a preferred predetermined dosage level comprises:

**[0036]** about 0.26 to 8.33% (w/v) of inulin in a soluble form;

**[0037]** about 0.0052 to 0.166 ppm (w/v) of Vitamin D<sub>3</sub> as cholecalciferol;

**[0038]** about 0.0026 to 0.083% (w/v) of soy isoflavones from concentrated extracts;

**[0039]** about 0.026 to 0.83% (w/v) of calcium in a biologically acceptable soluble calcium salts, preferably calcium lactate;

[0040] about 0.0052 to 0.166% (w/v) of magnesium in a biologically acceptable soluble magnesium salts, preferably magnesium glycerophosphate;

[0041] about 2.08 ppm to 66.67 ppm (w/v) of zinc in a biologically acceptable soluble zinc salts, preferably zinc citrate;

[0042] about 0.018 ppm to 0.58 ppm (w/v) of Vitamin K blend (1% phylloquinone);

[0043] about 0.01 to 0.417% (w/v) of ascorbic acid;

[0044] about 0.0052 to 0.166% (w/v) of maltol and 0.052 to 1.67% (w/v) of Insta\*Thick C-15L (containing carrageenan and maltodextrin) from Zumbro Inc., or about 0.0052 to 0.166% (w/v) of maltol and about 12.5 ppm to 400 ppm (w/v) of xanthan gums;

[0045] The following examples describe methods for preparing a beverage composition of the invention as a single strength (comprising, in this example, the daily predetermined amounts of the individual components) or as a beverage preparation in the form of a concentrate syrup (3x to 4x the daily predetermined amount).

### Method 1

[0046] **SINGLE STRENGTH FORMULA** (To make 960 mL = 4x240mL servings)

[0047] Heat approximately 180 mL deionized water to about 80 to 85°C.

[0048] Add 0.4g maltol to the hot water and stir until it is completely dissolved.

[0049] Add 4 g INSTA\*THICK C-15L™ to the above mixture and stir until it is completely dispersed.

[0050] Add 500 mg soy isoflavone extract to the above mixture and stir at 80 to 85°C for at least 10 minutes.

[0051] Filter the hot solution through 1.2  $\mu$ m glass fiber filter. Rinse the container with about 2x200 mL deionized water and filter the rinse through the same filter too.

[0052] To the above hot filtrate, add sequentially 14.28 g calcium lactate pentahydrate, 3.76 g magnesium glycerophosphate, 0.0532 g zinc citrate dihydrate, 1.344 g citric acid, 0.688 g malic acid, 0.0232 g sodium citrate dihydrate, and a

premix of 25 g sugar and 22.6 g inulin. Stir until no particulate remains. Then add 75 g sugar and stir until it is completely dissolved.

[0053] Cool the mixture to room temperature, add 2.5 g ascorbic acid, 0.0536 g Vitamin D<sub>3</sub> and 0.042 g Vitamin K blend (1% phylloquinone). Stir until the solids are dissolved.

[0054] Add optional flavors and colorants.

[0055] Adjust the volume to 960 mL with deionized water.

[0056] Divide the volume into four 240 mL parts for serving size.

**Method 2 (with Xanthan gum):**

[0057] **SINGLE STRENGTH FORMULA** (To make 960 mL = 4x240 mL serving)

[0058] Heat approximately 400 mL deionized water in a container to about 80 to 85°C.

[0059] Add 0.4 g maltol to the hot water and stir until it is completely dissolved.

[0060] Add 0.5 g of soy isoflavone extract to the above mixture and stir under 80 to 85°C until the mixture is clear.

[0061] While hot, filter the mixture through a 1.2 µm glass fiber filter. Rinse the container with about 2x40 mL deionized water and filter the rinse through the same filter.

[0062] To above filtrate, add sequentially 14.28 g calcium lactate pentahydrate, 3.76 g magnesium glycerophosphate, 0.0532 g zinc citrate dihydrate, 1.344 g citric acid, 0.688 g malic acid, 0.0232 g sodium citrate dihydrate granular, a premix of 100 g to 113.12 g sugar (depending on flavor) and 22.6 g inulin. In order to achieve the astringency/tartness associated with some flavors' character, the following ingredients have been added: 0.0308 g of tartaric acid in pink grapefruit; 0.03 g of fumaric acid in cranberry-raspberry; and 0.308 g of fumaric acid and 0.24 g of sodium citrate dihydrate granular in raspberry. Stir the contents until all solids are completely dissolved.

[0063] Cool the mixture to room temperature, and add 2.5 g ascorbic acid, 0.0536 g Vitamin D<sub>3</sub>, and 0.0424 g Vitamin K blend (1% phylloquinone).

[0064] Stir until solids are dissolved.

[0065] In high shear, disperse 0.096 g xanthan gums (KELTROL-T™) in about 40 mL hot deionized water at about 60°C. Cool the solution to room temperature.

[0066] Add the xanthan gum solution to step 6 above and mix well.

[0067] Add optional flavors and colorants.

[0068] Adjust the volume to 960 mL with deionized water.

[0069] Divide the volume into four 240 mL parts for serving size.

### **Method 3**

[0070] **CONCENTRATED SYRUP (4X) PREDETERMINED DOSAGE PREPARATION** (Diluted 1 part syrup to 3 parts water to make a single strength)

[0071] Prepare a mixture of maltol, Insta\*Thick C-15L, soy isoflavone extract, calcium salts, magnesium salts, zinc salts, and fruit acids in water at about 80 to 85°C;

[0072] While hot, filter the dispersion of (1) through a 1.2  $\mu\text{m}$  glass fiber filter and then cool down the filtrate to about 50°C;

[0073] Add a premix of inulin and sugar to the filtrate of (2) and cool the dispersion to room temperature;

[0074] Add to the mixture of (3) vitamins, flavors, colorants and optional ingredients dissolved in water; all the said ingredients are added with agitation.

### **Method 4: (with Xanthan gum; without Isoflavone)**

[0075] **SINGLE STRENGTH FORMULA** (To make 1200 mL = 4 x 300 mL servings)

[0076] Place 320 mL water to the batching container.

[0077] Add 145 grams of liquid sucrose to the batching container.

[0078] Place 160 mL water in a separate container. With good shear, add 22.6 grams inulin and mix until all solids are completely dissolved. Transfer to the batching container.

[0079] Slowly add 15.7 grams calcium lactate to the batching container with fast agitation.

[0080] Place 80 mL water in a separate container. With high shear, disperse 3.2 grams vitamin premix, and transfer to the batching container.

[0081] In the composition of Example 8 herein, dissolve 1.344 grams citric acid, 0.6884 grams malic acid, and 0.0232 grams sodium citrate in a separate container, and transfer to the batching container.

[0082] In the composition of Example 9 herein (control w/ 80% citric and 80% malic acids reduction, and 10% Xanthan gum increase formula), dissolve 0.269 grams citric acid, 0.134 grams malic acid, and 0.0232 grams sodium citrate in a separate container, and transfer to the batching container.

[0083] In the composition of Example 10 herein (control w/ 100% Citric and 100% Malic acids reduction, and 10% Xanthan gum increase formula), dissolve 0.0 grams citric acid, 0.0 grams malic acid, and 0.0232 grams sodium citrate in a separate container, and transfer to the batching container.

[0084] Place 160 mL water in a separate container. With good shear, add 4.08 grams magnesium lactate and 2.12 grams monosodium phosphate and transfer to the batching container. Rinse the container with approximately 20 mL water and add to the batching container. Mix the contents of the batching container well for about 10 minutes.

[0085] Meanwhile:

[0086] In Example 8, place 160 mL water in a separate container. With high shear, disperse 0.48 grams xanthan gums until the solution is free of fish-eyes. Transfer the solution to the batching container with good agitation.

[0087] In Example 9, place 160 mL water in a separate container. With high shear, disperse 0.528 grams xanthan gums until the solution is free of fish-eyes. Transfer the solution to the batching container with good agitation.

[0088] In Example 10, place 160 mL water in a separate container. With high shear, disperse 0.528 grams xanthan gums until the solution is free of fish-eyes. Transfer the solution to the batching container with good agitation.

[0089] In a separate container, dissolve 0.13 grams zinc gluconate in hot water (140-150 deg F) and with agitation, transfer to the batching container. Rinse the separate container with water and add to the batching container.

- [0090] Add optional flavors to the batching container with good agitation.  
Add optional colors.
- [0091] For beta carotene and orange emulsion, add with hot water (140-150 deg F).
- [0092] Adjust the volume to 1200mL with water.
- [0093] Divide the total volume into 4 x 300 mL parts for serving size.

### Method 5: (with Xanthan gum; without Isoflavone)

[0094] **CONCENTRATED SYRUP (4X) PREDETERMINED DOSAGE**  
**PREPARATION** (Diluted 1 part syrup to 3 parts water to make a single strength)

- [0095] With high shear, prepare a mixture of sugar, inulin, and calcium salts;
- [0096] Add dispersed xanthan gums to the mixture;
- [0097] Add vitamin premix to the mixture;
- [0098] Add citric acid, malic acid, sodium citrate to the mixture.
- [0099] With high shear, add magnesium salts, and phosphate salts to the mixture.
- [0100] Add dissolved zinc salts to the mixture.
- [0101] Add optional flavors and colors.
- [0102] Ingredients are added with good agitation.
- [0103] Some optional colors are added with hot water.
  
- [0104] The beverage composition can be pasteurized through tunnel pasteurization or hot-fill techniques. A high temperature/short time condition is desirable for retaining maximum product quality. Alternatively, the beverage composition can be prepared with cold-fill techniques in conjunction with preservation by the addition of preservatives including, but not limited to, potassium benzoate and potassium sorbate. Carbonation may also be performed

to any desired volume, with an antifoaming (AF) agent such as AF emulsion (30% polydimethylsiloxane).

**[0105]** The above description related to forming the composition in the form of a beverage. With this description in mind, it is to be appreciated that conventional food processing techniques may be employed to prepare other forms of the composition, including powders, pastes, bars, and cookies, collectively "solid supplement compositions." Examples 11 through 13 herein describe representative compositions in the form of cookies, including inulin and calcium, along with Vitamins A and E.

**[0106]** The composition provides the necessary nutrients for preventing osteoporosis and also includes the principal components for enhancing bioavailability and metabolism of those nutrients. The principal components to improve bone density are believed to be calcium, magnesium, phosphorus, Vitamin D and Vitamin K. It is believed that the described composition gives better results than have heretofore been observed in prior art teachings.

**[0107] Example 1**

Formula for Orange Peach Flavored Beverage

INGREDIENT	AMOUNT, g (per 240 mL serving)
Inulin	5.65
Sugar	25.0
Calcium lactate, pentahydrate	3.57
Magnesium glycerophosphate	0.94
Zinc citrate, dihydrate (30%)	0.0133
Citric acid	0.336
Malic acid	0.172
Sodium citrate, dihydrate granular	0.0058
Ascorbic acid	0.625
Vitamin D <sub>3</sub> (0.25%)	0.0134
Vitamin K, 1% phylloquinone	0.0105
Soy isoflavones (40 to 50% concentrate)	0.1 to 0.125
Maltol	0.10
INSTA*THICK C-15L™	1.0
Natural orange flavor	0.4056
Natural peach flavor	0.312
Natural red colorant, cochineal extract	0.048
Natural orange emulsion colorant	0.012

**[0108] Example 2**

Formula for Pink Grapefruit Flavored Beverage

INGREDIENT	AMOUNT, g (per 240 mL serving)
Inulin	5.65
Sugar	25.5
Calcium lactate, pentahydrate	3.57
Magnesium glycerophosphate	0.94
Zinc citrate, dihydrate (30%)	0.0133
Citric acid	0.336
Malic acid	0.172
Tartaric acid	0.0077
Sodium citrate, dihydrate granular	0.0058
Ascorbic acid	0.625
Vitamin D <sub>3</sub> (0.25%)	0.0134
Vitamin K, 1% phylloquinone	0.0105
Soy isoflavones (40 to 50% concentrate)	0.1 to 0.125
Maltol	0.10
INSTA*THICK C-15L™	1.0
Natural pink grapefruit flavor	0.3631
Natural red colorant, cochineal extract	0.0503

**[0109] Example 3**

Formula for Citrus Berry Flavored Beverage

INGREDIENT	AMOUNT, g (per 240 mL serving)
Inulin	5.65
Sugar	25.0
Calcium lactate, pentahydrate	3.57
Magnesium glycerophosphate	0.94
Zinc citrate, dihydrate (30%)	0.0133
Citric acid	0.336
Malic acid	0.172
Sodium citrate, dihydrate granular	0.0198
Ascorbic acid	0.625
Vitamin D <sub>3</sub> , CWS (0.25%)	0.0134
Vitamin K, 1% phylloquinone	0.0105
Soy isoflavones (40 to 50% concentrate)	0.1 to 0.125
Maltol	0.1
INSTA*THICK C-15L™	1.0
Natural raspberry flavor	0.24
Natural Tangerine- Orange flavor	0.156
Cochineal extract	0.0499
Beta carotene 2% water dispersion	0.013

**[0110] Example 4**

Formula for Raspberry Flavored Beverage

INGREDIENT	AMOUNT, g (per 240 mL serving)
Inulin	5.65
Sugar	25.5
Calcium lactate, pentahydrate	3.57
Magnesium glycerophosphate	0.94
Zinc citrate, dihydrate (30%)	0.0133
Citric acid	0.336
Malic acid	0.172
Fumaric acid	0.0077
Sodium citrate, dihydrate	0.0658
Ascorbic acid	0.625
Vitamin D <sub>3</sub> , CWS (0.25%)	0.0134
Vitamin K, 1% phylloquinone	0.0105
Soy isoflavones (40 to 50% concentrate)	0.1 to 0.125
Maltol	0.1
INSTA*THICK C-15L™	1.0
Natural raspberry flavor	0.312
Cochineal extract	0.24

**[0111] Example 5**

Formula for Cranberry Raspberry Flavored Beverage

INGREDIENT	AMOUNT, g (per 240 mL serving)
Inulin	5.65
Sugar	25.0
Calcium lactate, pentahydrate	3.57
Magnesium glycerophosphate	0.94
Zinc citrate, dihydrate (30%)	0.0133
Citric acid	0.336
Malic acid	0.172
Fumaric acid	0.0075
Sodium citrate, dihydrate	0.0058
Ascorbic acid	0.625
Vitamin D <sub>3</sub> , CWS (0.25%)*	0.0134
Vitamin K, 1% phylloquinone	0.0105
Soy isoflavones (40 to 50% concentrate)	0.1 to 0.125
Maltol	0.1
INSTA*THICK C-15L™	1.0
Natural cranberry flavor	0.2086
Natural raspberry flavor	0.0751
Cochineal extract	0.36

**[0112] Example 6**

Formula for Citrus Blend Flavored Beverage

INGREDIENT	AMOUNT, g (per 240 mL serving)
Inulin	5.65
Sugar	25.0
Calcium lactate, pentahydrate	3.57
Magnesium glycerophosphate	0.94
Zinc citrate, dihydrate (30%)	0.0133
Citric acid	0.336
Malic acid	0.172
Sodium citrate, dihydrate	0.0058
Ascorbic acid	0.625
Vitamin D <sub>3</sub> , CWS (0.25%)	0.0134
Vitamin K, 1% phylloquinone	0.0105
Soy isoflavones (40 to 50% concentrate)	0.1 to 0.125
Maltol	0.1
INSTA*THICK C-15L™	1.0
Natural pink grapefruit flavor	0.1728
Natural orange flavor	0.2074
Natural lemon flavor	0.3110
Beta carotene	0.2208

**[0113] Example 7**

Formula for Lemon Lime Flavored Beverage

INGREDIENT	AMOUNT, g (per 240 mL serving)
Inulin	5.65
Sugar	25.5
Calcium lactate, pentahydrate	3.57
Magnesium glycerophosphate	0.94
Zinc citrate, dihydrate (30%)	0.0133
Citric acid	0.336
Malic acid	0.172
Fumaric acid	0.03
Sodium citrate, dihydrate	0.0058
Ascorbic acid	0.625
Vitamin D <sub>3</sub> , CWS (0.25%)	0.0134
Vitamin K, 1% phylloquinone	0.0105
Soy isoflavones (40 to 50% concentrate)	0.1 to 0.125
Maltol	0.1
INSTA*THICK C-15L™	1.0
Natural lemon-lime flavor	0.720
Beta carotene 2% water dispersion	0.01

**[0114] Example 8**

Formula for Orange Peach Flavored Beverage w/out Soy Isoflavones:  
Control Formula

INGREDIENT	AMOUNT, g (per 300 mL serving)
Inulin	5.65
Sugar	36.25
Calcium lactate, pentahydrate	3.92
Magnesium lactate	1.02
Monosodium phosphate, anhydrate	0.53
Zinc gluconate (30%)	0.0314
Citric acid	0.3360
Malic acid	0.1721
Sodium citrate, dihydrate	0.0058
Vitamin Premix	0.800
Xanthan Gum	0.120
Natural orange flavor	1.1100
Natural peach flavor	1.1650
Natural red colorant, cochineal extract	0.060
Natural orange emulsion colorant	0.028

**[0115] Example 9**

Formula for Orange Peach Flavored Beverage w/out Soy Isoflavones:

80% Citric and 80% Malic Acid Reduction and 10% Increased Xanthan Gum Formula

INGREDIENT	AMOUNT, g (per 300 mL serving)
Inulin	5.65
Sugar	36.25
Calcium lactate, pentahydrate	3.92
Magnesium lactate	1.02
Monosodium phosphate, anhydrate	0.53
Zinc gluconate (30%)	0.0314
Citric acid	0.0672
Malic acid	0.0344
Sodium citrate, dihydrate	0.0058
Vitamin Premix	0.800
Xanthan Gum	0.1320
Natural orange flavor	1.1100
Natural peach flavor	1.1650
Natural red colorant, cochineal extract	0.060
Natural orange emulsion colorant	0.028

**[0116] Example 10**

Formula for Orange Peach Flavored Beverage w/out Soy Isoflavones:

100% Citric and 100% Malic Acid Reduction and 10% Increased Xanthan Gum Formula

INGREDIENT	AMOUNT, g (per 300 mL serving)
Inulin	5.65
Sugar	36.25

Calcium lactate, pentahydrate	3.92
Magnesium lactate	1.02
Monosodium phosphate, anhydrate	0.53
Zinc gluconate (30%)	0.0314
Citric acid	0.0000
Malic acid	0.0000
Sodium citrate, dihydrate	0.0058
Vitamin Premix	0.800
Xanthan Gum	0.1320
Natural orange flavor	1.1100
Natural peach flavor	1.1650
Natural red colorant, cochineal extract	0.060
Natural orange emulsion colorant	0.028

**[0117] Example 11**

Formula for Soft Oatmeal Cookies: Temperature at 275 F at 6.5 MIN, dye size-1 1/2 inches, wire cut 18 grams; Kitchenaid Blender

INGREDIENT	AMOUNT	Mixing Speed
Raisin paste	7 oz	1/2 LOW
Crystalline Fructose	10 oz	
Granulated sugar	7 oz	
Inulin	1# 4 oz	
Brown sugar	4 oz	
Cane juice, Florida syrup	6 oz	
Glycerine	6 oz	1 LOW 4 HIGH
Natural butter flavor	15 grams	
Natural vanilla flavor	40 grams	
Liquid egg whole	4 oz	
Water	2 oz	
Ammonia	8 grams	
Cloves	1 gram	
Nutmeg	1.4 grams	
Oleo	14 oz	3 LOW
GMS 90	15 grams	
Vitamin E	6 grams	
Calcium carbonate	5.7 oz	
Ascorbic acid	5.6 oz	
Soda	18 grams	
Pastry flour, unbleached	1# 4 oz	
All spice	2 grams	4 LOW
Wright premix	5.3 oz	
Cinnamon	37 grams	
Quick oats	1# 3oz	
Regular oats	1#	
Double baking powder	6 grams	
Cinnamon flavor, natural	15 grams	
Maple flavor, natural	10 grams	
Raisins, midget	12 oz	1/2 LOW

**[0118] Example 12**

Formula for Soft Brownie Cookies with KOKO Bits: Temperature at 275 F at 6.5 MIN, dye size-1 1/2 inches, wire cut 18 grams; Kitchenaid Blender

INGREDIENT	AMOUNT	Mixing Speed
Crystalline Fructose	1# 2 oz	1/2 LOW
Granulated sugar	10 oz	1 HIGH
Inulin	1# 4 oz	
Cane juice, Florida syrup	6 oz	
Date paste	4 oz	
Natural butter flavor	25 grams	1 LOW 4 HIGH
Natural vanilla flavor	50 grams	
Devils food flavor	3 grams	
Liquid egg whole	4 oz	
Chocolate flavor	5 grams	
Glycerine	4 oz	
Water	1 oz	
Ammonia	8 grams	
Milk chocolate flavor	10 grams	
Oleo	14 oz	
Vitamin E	6 grams	3 LOW
GMS 90	15 grams	
Wright premix	5.3 oz	
Double baking powder	15 grams	
Cocoa dutch	10 oz	2 LOW
Soda	18 grams	
Calcium carbonate	5.7 oz	
Cocoa black	40 grams	
Ascorbic acid	5.6 oz	
Pastry flour, unbleached	1# 14 oz	
KOKO bits	10 oz	1/2 LOW

**[0119] Example 13**

Formula for Soft Peanut Butter Cookies: Temperature at 275 F at 6.5 MIN, dye size-1 1/2 inches, wire cut 18 grams; Kitchenaid Blender

INGREDIENT	AMOUNT	Mixing Speed
Crystalline Fructose	10 oz	
Inulin	1# 4 oz	1/2 LOW
Granulated sugar	12 oz	
High fructose corn syrup	9 oz	
Date paste	6 oz	
Glycerine	9 oz	
Water	2 oz	
Ammonia Bicarbonate	8 grams	
Natural butter flavor	25 grams	
Natural vanilla flavor	10 grams	
Natural peanut flavor	30 grams	
Liquid egg whole	4 oz	
Vitamin E	6 grams	
GMS 90	15 grams	
Peanut butter	12 oz	
Oleo margarine	7 oz	3 LOW
Calcium carbonate	5.7 oz	
Peanut flour	7 oz	2 LOW
Wright premix	5.3 oz	
Salt	8 grams	
Double baking powder	15 grams	
Soda	18 grams	
Ascorbic acid	5.6 oz	
Pastry flour, unbleached	1# 12.5 oz	
<u>Peanut splits (halves)</u>	<u>8 oz</u>	<u>1/2 LOW</u>

**[0120]** In the preceding detailed description, the invention is described with reference to specific embodiments thereof. It will, however, be evident that various modifications and changes may be made thereto without departing from the broader spirit and scope of the invention as set forth in the claims. The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense.